

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the following remarks.

STATUS OF CLAIMS

Claims 1-47 remain in this application.

Claims 1 and 47 are the only independent claims. These claims have been amended to additionally recite that the oil-in-water emulsion is a fluid, homogenized, UV-photoprotective oil-in water emulsion, the emulsion being macroscopically and microscopically stable for a period of time of at least 30 days in the absence of phase separation. The underlined language has been added to the generic claims to emphasize these distinctive features of the invention relating to stability as well as those features apparent from the original claim language. The word "fluid" finds support at least in paragraphs [0023] and [0153] of the as-filed specification. The word "homogenized" finds support throughout the original specification, including paragraphs [0050]-[0054]. The phrase "macroscopically...separation" has basis in the original specification, paragraphs [0007], [0008] and [0153].

Minor additional corrections have been made throughout the claims to bring the references to portion of the structures into conformity with the structures themselves.

It is clear from the foregoing that no new matter has been introduced by these amendments.

CLAIM FOR FOREIGN PRIORITY

The Examiner's acknowledgment of the foreign priority claim and the certified copy of FR 03/04648 is noted, with appreciation.

INFORMATION DISCLOSURE STATEMENT

The Examiner has acknowledged the Information Disclosure Statement filed April 14, 2004. Applicants thank the Examiner for returning a fully initialed copy of applicant's Form PTO-1449. A further Information Disclosure Statement is filed herewith.

STATEMENT OF SUBSTANCE OF INTERVIEW

Applicant's representatives thank Examiner Dodson for the courtesy of the personal interview on December 11, 2007. In the interview, it was first clarified that the secondary reference was intended to be EP 1 008 586, not WO 02/055046, and that Habeck et al. US 6,436,373 B1 corresponds to EP 1 008 586. The teachings of the primary reference EP 0 864 320, corresponding to Simonnet et al. US 6,126,948, as well as the secondary reference, were briefly discussed. It was agreed that applicant would amend the claims to emphasize the unexpected stability of the instant emulsion and to submit arguments as to why the claims distinguish over the cited references. Applicants' representative also noted that there was comparative data relating to the unexpected stability of the instant emulsion. Finally, it was agreed that the filing of a terminal disclaimer would obviate the obviousness-type double patenting rejection with respect to copending Appln. No. 10/823,735.

DOUBLE PATENTING REJECTION

Claims 1-47 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-29 of copending Appln. No. 10/823,735. As confirmed in a telephone conversation with

Examiner Dodson on December 14, 2007, Appln. No. 10/823,735 has been abandoned by failure to file a response to the outstanding Official Action therein. This obviates the obviousness-type double patenting rejection herein and there is no longer a need to file a terminal disclaimer as agreed upon at the interview. Withdrawal of the provisional obviousness-type rejection is believed to be in order and is earnestly solicited.

CLAIM REJECTIONS - 35 U.S.C. § 103

Claims 1-47 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over L'Oreal EP 0 864 320 A(R1), which is equivalent to Simonnet et al. US 6,126,948, in view of WO 02/055046 A1(R2), corrected to EP 1 008 586, which is equivalent to Habeck et al. US 6,436,373. For simplicity, this will be treated as a rejection based on EP '320/US '948 in view of EP '596/US '373. Applicant submits that all of the claims as now in the application are patentable over this combination of references.

The instant claims are drawn to a fluid, homogenized UV-photoprotective oil-in-water emulsion, macroscopically and microscopically stable for a period of time of at least 30 days in the absence of phase separation, the oil globules of which having an average size of at most 500 nm, containing particles of at least one ionic polymer and at least one UV radiation-screening system comprising at least one 4,4'-diarylbutadiene UV-A-screening agent, as set forth in Claim 1; and to a method for the photoprotection of the skin, lips and/or hair against the damaging effects of UV radiation, comprising topically applying thereon a thus effective amount of said emulsion, as set forth in Claim 47. The remaining claims depend, directly or indirectly, from Claim 1.

The primary reference EP '320/US '948 discloses UV cosmetic oil-in-water emulsions comprising oil globules, which have a mean particle size of 500 nm and contain at least one ionic polymer. As noted by the Examiner, this reference does not disclose the presence of 4,4-diarylbutadiene UV-A screening agents. However, sunscreens are taught to be an optional ingredient therein.

As explained in applicant's specification, a family of organic UV-A screening agents which are particularly effective in the UV-A region is 1,4-benzene[di(3-methylidene-10-camphorsulfonic)] acid and its salts. Camphorsulfonic acid derivatives are indeed among the many possible sunscreens disclosed in EP '320/US '948. However, it has been found that introduction of this type of screening agent into fine oil-in-water emulsions stabilized with particles of ionic polymers rapidly leads to their destabilization. This forces the formulator to use them in very low concentrations and to limit the photoprotective efficacy in particular in the UV-A domain. Therefore, the problem facing the present inventor was how to provide fine anti-sun/sunscreen oil-in-water emulsions based on particles of ionic polymer which are stable and which may contain organic screening agents active in the UV-A of comparable efficacy to that of 1,4-benzene[di(3-methylidene-10-camphorsulfonic)] acid and its salts without the destabilization which occurs when that camphorsulfonic acid derivative is used.

The secondary reference, EP '586/US '373, discloses oligomeric 4,4-diarylbutadiene UV-A screening agents. 4,4-Diarylbutadiene sunscreens have also been described as optional organic sunscreens in the previously cited WO 02/055046 and its equivalent Lennon et al. US 6,855,311. However, the art does not suggest that stable oil-in-water emulsions of appropriate particle size (average of at most 500 nm) could not be obtained using a 1,4-benzene[di(3-methylidene-10-

camphorsulfonic)] acid UV-A sunscreen but could be obtained using a 4,4-diarylbutadiene UV-A sunscreen. Clearly, it is not obvious that a 4,4-diarylbutadiene sunscreen would work where a 1,4-benzene[di(3-methylidene-10-camphorsulfonic)] acid sunscreen would not.

In support of applicant's position, data is presented below for testing carried out by the present inventor. The sunscreens tested were 1,4-benzene[di(3-methylidene-10-camphorsulfonic)] acid, which is also known as MEXORYL SX, and 1,1-dicarboxy-(2',2'-dimethylpropyl)-4,4-diphenylbutadiene, also identified as compound (f) on page 13 of the original specification.

Comparative tests

The following O/W emulsions were prepared:

Composition	Example E1 (Sunscreen of the invention)	Example E2 (Prior art sunscreen)
Diethyleneglycol/Phthalate/Isophthalate/1,4-cyclohexane-dimethanol copolymer (AQ 38 S - Eastman Chem.)	2%	2%
Glycerin	5%	5%
Preservative	0.3%	0.3%
EDTA (séquestrant)	0.1%	0.1%
1,4-benzene[di(3-methylidene-10-camphorsulphonic)] acid		5% MA
Triethanolamine		qsp pH= 7
Demineralized water	qsp 100%	qsp 100%
Vaseline oil	10%	10%
Octylmethoxycinnamate	7%	7%
1,1 dicarboxy-(2',2'-dimethylpropyl)-4,4-diphenylbutadiene (compound f)	5%	
Octyldodecanol	5%	5%
Alkyl C12-15 benzoate	15%	15%
Average size of the oil drops	345 nm	1477 nm
Polydispersity index (PI)	PI 0.16	PI 0.26

The two formulations E1 and E2 were prepared under the same conditions as indicated in the present application. Dispersion, at room temperature, of the oily phase into the aqueous phase was prepared with vigorous stirring. The emulsion was homogenized at a pressure of 600 bar (3 passes) with a high pressure homogenizer of the type Rannie; the emulsion being brought to room temperature between each pass. The determination of stability is carried out after centrifugation at 10000 rpm during 20 minutes, at 25°C on a Beckmann Optima TLX 100 apparatus.

The average size of the oil drops and the polydispersity index (PI) are measured for each obtained emulsion.

The polydispersity index is between 0 and 1 and corresponds to the distribution width and is calculated with the average size of the distribution. The larger this index, the more the distribution is heterogeneous. A difference of 0.1 is very significant.

The results of the test show clearly that:

- 1) The use of 1,4-benzene[di(3-methylidene-10-camphorsulfonic)] acid (MEMORYL SX) in the comparative example does not permit a fine O/W emulsion having an average size of oil drop lower than or equal to 500 nm, contrary to use of the representative diarylbutadiene, 1,1-dicarboxy-(2',2'-dimethylpropyl)-4,4-diphenylbutadiene in the emulsion 1.
- 2) The comparative emulsion is unstable (separation in two phases) contrary to the claimed emulsion 1 containing as UVA filter 1,1-dicarboxy-(2',2'-dimethylpropyl)4',4-diphenylbutadiene in the emulsion E1.

Only the diarylbutadiene sunscreen gave the desired stability. In accord with the present invention, a fluid, homogenized oil-in-water emulsion, macroscopically and microscopically stable for a period of at least 30 days in the absence of phase separation, can be obtained using a 4,4-diarylbutadiene UV-A sunscreen, but not using the dicamphorsulfonic acid derivative. Not one of the cited prior art references evokes the technical problem above defined. In view of those documents, a skilled man in the art who wanted to solve this problem could not predict the use of a 4,4-diarylbutadiene as UVA filter in an oil-in-water emulsion in which the oil globules of

the emulsion have an average size of at most 500 nm, containing at least particles of ionic polymer and at least one UV radiation-screening system.

In fact, EP '320/US '948 discloses an oil-in-water emulsion in which the oil globules of the emulsion have an average size of at most 500 nm, containing at least particles of ionic polymer. Those specific emulsions may contain UV filters which can be lipophilic or hydrophilic, having UVA and/or UVB absorption properties.

According to this document, one skilled in the art would expect Mexoryl SX to be useful in such emulsions. This document does not suggest the destabilization of such emulsions which in fact occurs with this sunscreen nor does it suggest that a 4,4-diarylbutadiene UV-A sunscreen would be remarkably more stable.

WO 02/055046 discloses water/oil emulsions based on metal oxide pigments stabilized by an oligomer or a polymer derived from a polyolefin. The subject of this document does not concern oil-in-water emulsions in which the oil globules of the emulsion have an average size of at most 500 nm.

EP '586/US '373 teaches 4,4-diarylbutadiene sunscreens but does not suggest that they would be useful in oil-in-water emulsions as claimed herein in place of the dicamphorsulfonic acid derivatives which destabilize an emulsion of this kind and do not allow for particles small enough to remain without separation into two phases.

If the Examiner would like the comparative data presented above to be submitted in the form of a Declaration Under 37 C.F.R. § 1.132, she is asked to contact the undersigned at the number given below.

In view of the foregoing it is believed that all record rejections have been overcome. Further, favorable action in the form of a Notice of Allowance is believed to be next in order and is earnestly solicited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: December 20, 2007

By: /Mary Katherine Baumeister/
Mary Katherine Baumeister
Registration No. 26254

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620